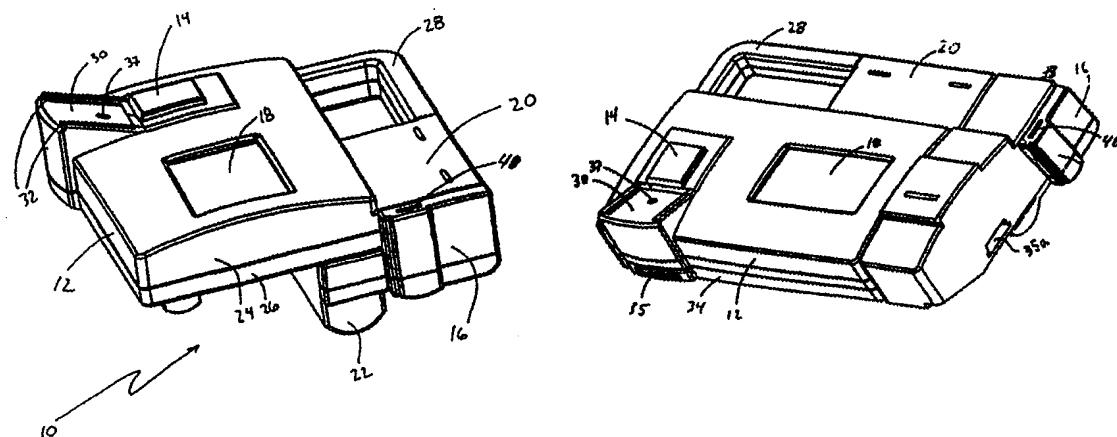


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : G01N 33/487		A1	(11) International Publication Number: WO 00/05581 (43) International Publication Date: 3 February 2000 (03.02.00)
(21) International Application Number:	PCT/US99/14699		
(22) International Filing Date:	30 June 1999 (30.06.99)		
(30) Priority Data:	09/119,983 21 July 1998 (21.07.98)	US	
(71) Applicant:	DIAMETRICS MEDICAL, INC. [US/US]; 2658 Patton Road, Roseville, MN 55113 (US).		
(72) Inventors:	ANDERSON, Carter, R.; 4383 Hamilton Drive, Eagan, MN 55123 (US). GIDDINS, David, T.; 955 Laurelwood, Carmel, IN 46032 (US). KURKOWSKI, James, D.; 10820 Runnymede Lane, Minnetonka, MN 55305 (US). THOMPSON, Robbi, T.; 5170 Kirkwood Avenue North, Lake Elmo, MN 55042 (US). SIN, Kee, Van; 9259 Hyland Creek Road, Lino Lakes, MN 55104 (US).		
(74) Agent:	MERSEREAU, C., G.; Nikolai, Mersereau & Dietz, P.A., 820 International Centre, 900 Second Avenue South, Minneapolis, MN 55402 (US).		

(54) Title: PORTABLE IMMEDIATE RESPONSE MEDICAL ANALYZER HAVING MULTIPLE TESTING MODULES



(57) Abstract

A portable device that includes a plurality of test modules for analyzing preselected concentrations of various body fluids of a patient. The portable diagnostic device interfaces and utilizes disposable cartridges and reagent diagnostic test strips and other fluid sample diagnostic devices to determine the amounts of preselected parameters in a patient's blood through either electrochemical, electrical, optical, or mechanical analysis. The disposable fluid sample diagnostic devices may include sample chambers with inlet ports, electrical, physical, or chemical sensors, in situ calibration media, a plurality of electrical interface terminals, and temperature control elements. An electrical interface interconnects the various test modules with one or more corresponding integrated circuits which in turn are electrically coupled to a common interactive display, printer, power supply, and communication ports.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

**PORTABLE IMMEDIATE RESPONSE MEDICAL ANALYZER
HAVING MULTIPLE TESTING MODULES**

The present application is a complete application claiming priority based on co-pending Provisional 5 Application Serial Number 60/053,406, filed July 22, 1997 and entitled "IMMEDIATE RESPONSE MEDICAL ANALYZER HAVING MULTIPLE TEST MODULES".

BACKGROUND OF THE INVENTION

I. Field of the Invention

10 The present invention is directed generally to a stationary or portable diagnostic system or electroanalytical systems for analyzing preselected characteristics of a patient's blood and other fluids. More particularly the present invention is concerned with 15 a portable diagnostic device or analytic instrument that includes a plurality of test modules for analyzing various body fluids of a patient, wherein the modules are coupled to a common display, printer, power supply, and communication ports. The portable diagnostic device 20 interfaces and utilizes disposable cartridges, reagent diagnostic test strips, or other means to determine, for example, a patient's blood pH, pO_2 , pCO_2 , Na^+ , Ca^{++} , K , hematocrit, glucose and/or other parameters including oxygen saturation, coagulation or hemoglobin fractions. 25 The modules may determine the parameters through a variety of methods such as electrochemical, electrical, optical, or mechanical analysis of a fluid biological sample extracted from the patient. The disposable cartridge may utilize a bank of sensors for the pertinent electroactive species to 30 provide input in the form of analog electrical signals for the relevant determinations.

II. Related Art

During clinical, surgical, diagnostic and other medical procedures the measurement of certain 35 physical/chemical characteristics or conditions of the blood and other fluids of a patient are useful in order to evaluate the condition of a patient. For example, a

-2-

patient's blood pH, pO_2 , pCO_2 , Na^+ , Ca^{++} , K , hematocrit, glucose and other parameters including oxygen saturation, coagulation or hemoglobin fractions may be measured. These conditions may provide important indications of the patient's stability including, for example, the efficiency of the blood/gas exchange occurring in the lungs of the patient, the relative acid/base balance, or the concentration of certain indicative ion species in the blood. Such determinations are particularly useful in emergency circumstances.

In the past, the equipment provided to make such determinations has typically been complex and permanently installed in a hospital laboratory. Also, the user operating the equipment has been oftentimes required to be a highly-trained and skilled technician, which thereby increases the cost of operating the equipment and limits the number of potential users. With such equipment, in order to analyze a sample of fluid from the patient, a sample must be drawn from the patient and delivered to the laboratory, avoiding all external contacts.

During the transfer and delivery, the drawn fluids may be kept in close proximity to ice packs in order to maintain sample integrity. The sample is then injected into a designated receptacle of the diagnostic equipment and the equipment operated to perform the diagnostics on the sample. This procedure is time consuming, labor intensive, and usually disadvantageous in the operating room, emergency room or other area of the hospital, or outside the hospital where time is of the essence. Hence, portable devices that reduce the time required to make accurate blood-gas and related determinations, in order that proper and more timely corrective steps may be taken, are highly sought.

Many situations arise where it is impractical to deliver a patient's fluid sample to a hospital laboratory in order to analyze the patient's blood analytes. It would be desirable for paramedics and in-home health care

-3-

providers, for example, to analyze a sample at the point of collection without having to first deliver a sample to a hospital laboratory. To this end, it would also be desirable to provide a single portable diagnostic device 5 capable of analyzing simultaneously several samples and/or conducting several electrochemical, electrical, optical, or mechanical analysis simultaneously or in rapid succession to determine, a patient's blood pH, pO_2 , pCO_2 , Na^+ , Ca^{++} , K^+ , hematocrit, glucose and other parameters including oxygen 10 saturation, coagulation or hemoglobin fractions.

There have been attempts at point-of-care blood-gas analysis. One on-site analytic device, described by Enzer et al in U.S. Patent 4,786,394, is designed for direct connection to a heart/lung machine to monitor critical 15 blood gases during open-heart surgery. It employs a discardable sensor cartridge which contains a bank of sensors for making the electrochemical determinations. A further patent to Enzer et al (U.S. Patent 4,397,725) also discloses a clinical blood chemistry analyzer in which a 20 discardable cartridge interfaces with an analytical machine. Although the analyzer may be utilized on-site during surgery, the device disclosed by Enzer remains relatively stationary and immobile. Morris et al in U.S. Patent 5,325,853 (of common assignment with the present 25 invention) disclose a self-calibrating disposable sensor system.

Carter et al in U.S. Patent 5,628,890 describe an electrochemical sensor for measuring the glucose concentration in a patient's blood. Such a sensor is 30 limited to the particular analyte being measured and requires an interface with an electrochemical sensor. Stark in U.S. Patent 5,433,197 describes a non-invasive glucose measurement device that requires illumination of the patient's eye with near infrared radiation. The 35 capability of the Stark device is limited to determining blood glucose. Phillips et al in U.S. Patent 5,563,042 describe a device that measures glucose concentration in

-4-

whole blood optically using a reflective reading apparatus and a whole blood glucose test strip.

A further reference is contained in U.S. Patent 4,849,340 to Oberhardt discloses a device that measures 5 coagulation in whole blood using a liquid assay device and method.

Although somewhat useful, such devices are limited in application and address only part of the drawbacks of prior systems. There remains a need for a rapidly responding, 10 portable blood chemistry analytical device. A need also exists for a single, portable, self-calibrating, instant activation, rapid response diagnostic device capable of simultaneous analysis of several samples and/or conducting several electrochemical, electrical, optical, or mechanical 15 analysis simultaneously or in rapid succession to determine, blood pH, pO_2 , pCO_2 , Na^+ , Ca^{++} , K, hematocrit, glucose and other parameters including oxygen saturation, coagulation or hemoglobin fractions. The present invention meets these needs and overcomes the disadvantages of prior 20 devices.

SUMMARY OF THE INVENTION

The present invention provides a point-of-care medical analyzer that enables an operator without special training or skills to obtain rapid, accurate blood-gas, glucose, and 25 other analyte determinations at the time and location the sample is drawn. The device is compact, light-weight, easily transported and ready for immediate use. The analyzer is designed for rapid processing of electrical signals generated by electrochemical, electrical, optical, 30 or mechanical sensors of an associated module having both calibration and sample determination modes and utilizing one-time use or disposable cartridges. The modules may be removed from the analytic device and interchanged.

The plug-in disposable electrochemical sensor 35 cartridge which may be similar to that depicted in the above-cited U.S. Patent 5,325,853, the entire contents of which are hereby incorporated by reference for any purpose,

-5-

employs an array of sensors, typically a bank of aligned sensors on a ceramic chip in a flow-through chamber. The flow-through chamber, as packaged, further contains a calibration medium retained in situ with respect to 5 corresponding sensors to be calibrated such that when the disposable cartridge is activated in conjunction with insertion into and electrical connection with the analytical device, calibration signals are produced by the sensors on the disposable cartridge which enables immediate 10 automatic calibration of the sensors. The sample may thereafter be introduced through an entry port in a manner which causes the calibration medium to be displaced from the flow-through chamber and replaced by the blood or other fluid sample then in direct contact with the sensors. The 15 array of electrochemical sensors then produces electrical signals in accordance with the characteristics of the sample.

The disposable sample cartridge carries a heater in the form of a thin or thick film resistor carried on the 20 sensor chip itself designed to bring the sample quickly to the temperature desired for the analytic determination based on an optical sensor and remote control from within the analytical device. Such a system is depicted in Hieb et al., U.S. Patent

25 5,232,667, assigned to the same assignee as the present invention, the entire disclosure of which is incorporated herein by reference for any purpose. Once the desired temperature is reached, the electrical signals from the electrochemical sensors are received and processed by the 30 portable analyzer and the results made available on a display and/or in printed form. Other suitable "cartridges" are used in association with the other modules.

It will be appreciated by those skilled in the art that the analytical instrument is required to provide only 35 the signal processing systems for calibration and measurement. The remote temperature sensing and control system provided in the portable instrument, for example,

controls only the electric input to a heater located in the disposable cartridge. There is no heating system, per se, in the analytical instrument. The heating control system preferably includes an IR probe or other remote temperature 5 sensing device which is used in association with a programmed control or set point temperature to rapidly establish and maintain the desired temperature in the disposable cartridge. Further details of the temperature control arrangement are contained in the above-referenced 10 patent issued to Hieb et al (5,232,667).

In operation, the fully portable analytical instrument is brought to the point of sampling, i.e., the location of the patient. A predetermined number of disposable cartridges are removed from a temperature-stabilized 15 packaging and inserted or plugged into corresponding modules of the analyzer. The instrument is activated; the sensors are calibrated automatically and the calibration electronically compensated with respect to an ensuing set of measurement signals. A sample of interest is obtained 20 from the patient and a portion may immediately be transferred to the sample inlet port of the calibrated sensor system on each disposable cartridge. The sample displaces the calibration medium to a storage chamber and avails the electrochemical sensors for an immediate sensing 25 of the corresponding species of interest in the sample. Other types of sensors including electrochemically active reagent test strips may be exposed to the sample and inserted into a corresponding module.

The user determines the particular needs for testing 30 and determines which modules to attach to the base unit of the immediate response medical analyzer. Plugging the disposable cartridges and inserting relevant sample strips into the respective module of the portable medical analyzer activates the system. The activation of the system also 35 activates the temperature control system which maintains the sensor chip, or equivalent, at the desired calibration and analysis temperature for those determinations that

require temperature control. If the sample within the cartridge is at a different temperature, the temperature control system reacts quickly and controls the sensors to restore the desired temperature to the system. Of course, 5 some determinations, including glucose measurement, do not require temperature control.

After the determinations have achieved equilibrium and the corresponding signals have been read by the analyzer, the analyzer computes the results based on the sensor 10 outputs. The results are made immediately available on a combination touch screen LCD display and as a printed record using an integral printer. It is anticipated that the entire operation from first insertion of the cartridges and activation of the system until printout of the results, 15 assuming the immediate availability of the sample, can be achieved in less than three minutes. In addition to the rapid availability, the results are also stored by the device in memory for later retrieval by touch screen, printer or to be sent via a communications port to an 20 external or remote computer or laboratory.

OBJECTS

It is accordingly a principal object of the present invention to provide a portable, rapidly responding, point-of-care medical device having several modules capable of 25 independently determining a plurality of predetermined analytes from a fluid biological sample.

Another object of the present invention is to provide a rapidly responding, portable medical analytical instrument capable of interfacing with several self-contained, self-calibrating, or pre-calibrated, disposable 30 fluid sample devices of varying construction.

Yet another object of the present invention is to provide a portable sophisticated medical analyzer capable of simplistic user friendly operation.

35 A further object of the invention is to provide a self-contained point-of-care blood analyte analyzer capable of instant activation and almost immediate response in

determining a patient's blood pH, pO_2 , pCO_2 , Na^+ , Ca^{++} , K^+ , hematocrit, glucose and other parameters including oxygen saturation, coagulation or hemoglobin fraction.

These and other objects, as well as these and other features and advantages of the present invention will become readily apparent to those skilled in the art from a review of the following detailed description of the illustrated embodiment in conjunction with the accompanying claims and drawings in which like numerals in the several views refer to corresponding parts.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1a is a perspective view of the multiple module portable point-of-care analyzer of the present invention;

Figure 1b is a perspective view of a multiple module similar to the analyzer of Figure 1a with an additional module attached;

Figure 2 is a partially exploded perspective view of the device of Figure 1 showing a module removed;

Figure 3 is a fragmentary, partially exploded, lower perspective view of the device showing a module removed from the analyzer;

Figure 4 is a partially exploded perspective view of the top section of the device of Figures 1 or 2, without the removed module and including a non-contact temperature sensor probe and print roll;

Figure 5 is a schematic system block diagram for one embodiment of the multi-module or multiple module portable medical analyzer of the invention;

Figure 6 is an electrical schematic illustrating the connection between a glucose module and the integrated circuit of the analyzer;

Figure 7 is a fragmentary perspective view of a cartridge receptacle interface with a cartridge inserted;

Figure 8 is a perspective view of a disposable cartridge for use with the analyzer of the invention;

Figure 9 is a schematic diagram of an analog interface subsystem associated with Figure 5;

Figure 10 is a partially exploded perspective view of an alternate embodiment of the portable point-of-care analyzer of the present invention; and

5 Figures 11-13 depict schematic block diagrams of examples of modules that interface with each of the modular interface system types depicted in Figure 5.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention includes a point-of-care and immediate response portable medical analyzer that features 10 automated calibration and analysis for a variety of uses. The analyzer includes several interchangeable modules that allow the user to analyze several samples or analyze one sample for several predetermined criteria at the point-of-care without extended delays. Thus blood-gas analysis 15 results can be made available to the attending physician, surgeon, or other health care provider within a minute or two after the drawing of a sample. Moreover, it takes no particular skill to operate the portable medical analyzer inasmuch as both calibration and sample analysis have been 20 automated in conjunction with a unique self-calibrating system. A disposable plug-in cartridge unit interfaces with the medical analyzing device or a reagent strip is automatically interfaced with an output system. While the illustrated embodiments described below are directed to 25 blood-gas and blood-electrolyte analysis, it will occur to those skilled in the art that these are meant as examples and are in no way intended to introduce limitations to the scope of the invention and that the system can be adapted to other analyses involving blood or other body sera 30 without departing from the essential premises of the invention. It will be appreciated from the views of Figures 1a-4 that one advantage of the portable analyzer of the invention is that it is mechanically simple and eliminates the need for medical personal to transport 35 samples to a plurality of diagnostic analyzers.

With this in mind attention is directed first to Figures 1a and 1b where a portable analytic device in

-10-

accordance with the present invention is shown generally at 10. The base unit device 10 includes a housing 12, a first permanent module 14, a second removable module 16, a touch screen interactive display 18, a printer 20, and a 5 replaceable power supply 22. The base unit enclosed in the housing 12 also includes an upper section 24 and a lower section 26, and includes a void area to define a handle 28. An attached removable second module is shown at 16. The first permanent module 14 includes a cartridge receptacle 10 30 having a pair of guide flange 32 to hold and guide the sides of a disposable cartridge 140 (see Figure 8) into the receptacle 30. As shown in Figure 1b, an additional module 33 which may be interposed between the module 16 and the basic analytical device 10. The embodiment of Figure 1b 15 notably further includes an additional interface section 34 which includes a plug receptacle 35 represents another interface to receive yet another measurement module having an input and output integrated into the basic analytical unit 10.

20 A remote temperature sensor 36 is positioned in the receptacle 30 (see Figure 4) beneath an opening 37, thereby providing for temperature measurements of the cartridge 140 as further described below. As best seen in connection with Figure 4, the interactive display 18 includes a touch 25 screen with an 8 x 8 grid mask 42 associated with an output LCD window or cover 44 which is fastened beneath an opening 46 in the top housing member 24.

The power supply 22 includes a battery pack, which supplies power through ON-OFF control to the 30 microprocessor, cartridge interface and the touch screen 18. Common voltages are supplied as needed within the processing circuitry through a variety of voltage converters which also supply the liquid crystal display bias and the back lighting for the touch screen 18. This 35 system is considered conventional to those skilled in the art, and further explanation is believed unnecessary.

Module 16 is a glucose meter that includes a

-11-

receptacle 48 for insertion of a test strip. Without any limitation intended, the module 16 may utilize, for example, the motherboard and test receptacle of a SURESTEP glucose meter available from Lifescan, Inc. Milipitas, 5 California. The motherboard and test strip receptacle are mounted to the module and are electrically coupled to a connector that interconnects a communication line and power supply to the internal electrical components contained within housing 12. A relay and control line may be added 10 to allow control of the power supplied to the module 16.

Module 33 may be capable of performing a coagulation assay such as PT (prothrombin time), PTT (activated partial thrombo-plastin time) or ACT (activated clotting time). This module may measure whole blood coagulation time and 15 includes a system for receiving a liquid sample into a reaction chamber containing a reagent material which reacts with the sample to perform the determination. The reaction can be monitored optically to determine the assay time. Such a system is illustrated and described in U.S. Patent 20 4,849,340 to Oberhardt, the details of which are deemed incorporated by reference herein for any purpose. The output signals from that module are digitized and processed within the module itself prior to being communicated to the base unit.

25 Those skilled in the art will appreciate that modules 14, 16 and 33 may be different sensors of suitable construction or additional examples include modified slightly to interface with electrical components of the present invention. Optionally, additional modular units 30 may be added in stacked or separate arrangements. The appropriate interconnects including communication and power supply links can be provided as direct plug-in linkages from the base unit and through other sensor modules. Without any limitation intended, dedicated removable sensor 35 modules may include a visible light sensing device that makes co-oximetry measurements such as total hemoglobin concentrations (tHb), oxyhemoglobin (O₂Hb),

-12-

carboxyhemoglobin (COHb) and methemoglobin (MetHb) of a blood sample contained in a cartridge or cuvette may be mounted in a module and interconnected with the present invention. Modules of this type are available from AVOX 5 Systems Incorporated of San Antonio, Texas. Those skilled in the art will appreciate that the mother board and optical bench of such a sensor may be removed and electrically connected within the housing 12 of the analytic device 10. An external connector may be used to 10 interconnect the sensor module's communication lines and power supply to the device 10. A relay with one control line may be added to allow control over the module by the device 10. Also, the controlling software may be modified to allow control of the module via the device 10.

15 Figures 2 and 3 illustrate the removeability of the second module 16. The module 16 locks onto the housing 12 (Figure 1a) may utilize a male and female quick release lock of known suitable construction. When the module 16 is locked in place, the electrical contacts 38 of the module 20 engage with the electrical contacts 40 protruding from the housing 12. Those skilled in the art will appreciate that a plurality of electrical contacts may be utilized to form a serial port or other electrical connection of known suitable construction to thereby interconnect the internal 25 electrical components of the module 16 with an integrated circuit and central processing unit (CPU) contained within the housing 12. The module 16 includes a receptacle 48 adapted for receiving a diagnostic test strip or electrochemical sensor of known suitable construction. The 30 module 33 of Figure 1b attaches to the housing 12 in a similar manner and includes pass-through interfaces and housing lock system to accommodate the module 16 in a piggyback or tandem stacked arrangement. Note that module 35 33 also has a further plug receptacle 35a situated to accommodate yet another modular sensor.

In accordance with the operation of the portable medical analyzer of the invention, a typical operating

-13-

system is shown in block diagram in Figure 5. Additional details of subsystems are illustrated in Figures 6 and 9. The interface of module 16 with the integrated circuit contained within housing 12 is depicted in Figure 6 and the 5 analog interface system is depicted in Figure 8.

Additional information can be gleaned with reference to the schematic block diagram of Figure 5. The system is operated by a programmed central processing unit 70 which operates in conjunction with a voltage controlled 10 oscillator 72, real-time clock 74 with associated non-volatile random access memory (novram) 76 random access memory (RAM) 78 and erasable programmable read only memory (EPROM) 80. The system further includes a communication integrated circuit 82 (RS232 with interface 84 and a 15 typical circuit connector 86). Also included is an interface 88 for the interactive touch screen display 18. A printer interface 90 for printer output and LCD interface 92 are also shown. Various switches and an alarm or beeper device 94 are connected through a bit output device at 96. 20 An analog interface 98 interconnects the heater system 100, sensor interface 102 and module interfaces 104-110. Those skilled in the art will appreciate that additional module interfaces 112-116 may be interconnected with integrated circuit 82 via a multiplexor 118. Additionally, module 25 interfaces 120-124 may be directly connected to the central processing unit 70. In this manner, those skilled in the art will appreciate that a variety of modules having various processing components may be rendered compatible with the present portable device 10.

30 For example, Figure 6 shows a glucose measuring module of common known construction electrically coupled to an immediate response medical analyzer (IRMA). Figure 11 depicts a typical module of a class designed to interface with the instrument 10 through any of interface modules and 35 may include a CPU 150 connected to the module interface through a serial input/output device. The module further typically includes a sensor interface 154 with associated

-14-

measurement circuitry 156 signal conditioning system 158 and A/D signal converter 160. A CPU controlled DAC signal generator 162 provides an analog interface with a temperature control system and sensor interface 154. The 5 module depicted in Figure 12 is of a class that are designed to connect to a module interface through a multiplexer and communication IC as at 118 and 82. This includes any of the module interfaces 112, 116. It will be appreciated that the modules 16 and 33 are compatable with 10 this type of interface. Figure 13 depicts yet another type of connected device compatable with the module interfaces 104- 110.

With respect to Figure 9, it will be appreciated that once the disposable cartridge is plugged into the analyzer 15 and the analyzer is turned on, calibration signals are almost immediately available on a clock controlled or prioritized channel selective interface bus as at 130 such that by employing a serial clock, the serially obtained data available on the bus 130 can be processed by a serial 20 to parallel converter 132 interfacing with the central processing unit 70 to sort out the multiple signals being received from A-to-D converters 134-142. Corrective data where applicable and reference measurements are provided via the A-to-D converter 142 from a multiplexer channel 25 control 144 that receives input from a variety of sources including barometric pressure sensor, temperature, reference electrode signals and an oxygen bias signal, if used, from the sensor interface 102. The clock controlled CPU interfaces with both the multiplexer channel control 30 and the remaining electrochemical sensors via the serial to parallel converter in a manner which uses the signals together with the available calibration condition data from the multiplexer via A-to-D converter 142 to accurately calibrate each of the species sensors for subsequent use in 35 making a determination in the sample.

It will be appreciated that in this manner, each disposable cartridge is automatically individually

calibrated with respect to the measurements to be made once connected to the analyzer and activated. Determination of each sample is then made pursuant to an individualized calibration based on the disposable cartridge itself and 5 not based on calibration of any of the components in the portable analytical device.

Figure 8 depicts a perspective view of the disposable cartridge 34 designed for use in association with the medical analyzer 10 of the invention. The cartridge 34 10 includes a substantially planar base member or plate 146 and a housing 148 fixed to the base member 146. One end of the cartridge is formed to include a handle with a gripping flange 150 to obtain a better grasp of the cartridge 34. Side flange members 152 extend from the sides of the planar 15 base and slide under guide flanges 32 of the cartridge receptacle 30. Figure 7 shows the cartridge 34 aligned and engaged with receptacle 30 and having an injection syringe 154 positioned to introduce a sample into a sample port 156.

20 The cartridge is further provided with an array of electrical leads or terminals as at 158 configured to connect with corresponding terminals in the analytical instrument cooperating in the exchange of electrical signals between the analytical instrument and cartridge in 25 a well-known manner. These terminals connect to corresponding conductors (not shown) of the receptacle 30 which provide all necessary input and output connections to control the functions and transmit the necessary signals between the cartridge and the analytical instrument. The 30 cartridge housing 148 further defines a flow-through analytical cell chamber or volume containing an array of electrochemical sensors 160-168 connected to a relatively larger waste receptacle chamber 170. The cartridge waste volume 170 includes a retention maze in the form of a 35 plurality of partitions as at 172. As recognized above, the cartridge and module 14 are described in greater detail in U.S. Patent 5,325,853, the entire disclosure of which

-16-

has been incorporated herein by reference.

An alternate embodiment of the portable device 10 is shown generally at 200 in Figure 10. The device is adapted for receiving a cassette 202 in which is electrically 5 integrated a plurality of testing modules 204-208. The cassette 202 is provided with a cover that engages with the base of cassette 202. A rechargeable, replaceable battery pack 212 is shown elevated above the portable device 200. The device 200 also includes an interactive display 214 and 10 printer 216. The cassette 202 includes electrical connectors that electrically interconnect each module 204-208 with the electrical components contained within the device 200 (including a central processing unit and integrated circuit). The modules 204-208 may be removed 15 from the cassette 202 and are interchangeable. In this manner, the user may either analyze several samples using similar modules or may select different modules to perform varying analysis and diagnostics of a single sample.

This invention has been described herein in 20 considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use embodiments of the example as required. However, it is to be understood that the invention can be 25 carried out by specifically different devices and that various modifications can be accomplished without departing from the scope of the invention itself.

What is claimed is:

CLAIMS

1. A portable point of care medical analyzer that enables an operator to obtain rapid analytic results for diverse determinations comprising:

5 (a) a base unit having a main CPU and including signal processing devices and circuitry for rapid processing of electrical signals generated by electrical, electro-chemical, optical or mechanical sensors of one or more associated modules;

10 (b) at least one permanent analytical module integral with said base unit with removable electro-chemical sensors for making a plurality of determinations characteristic of a fluid serum sample;

15 (c) one or more types of sensor modular interface units for connecting and interfacing between one or more removable module units and said base units;

20 (d) one or more dedicated removable sensor modules for making specific determinations designed to attach to said base unit and connect electrically to a specific type of modular interface;

25 (e) wherein the combination of said base unit signal processing devices and circuitry and said module interface unit enables direct utilization of the output signals from said removable modules; and

30 (f) common output devices in said base unit for providing visual or printed display of determinations from all modules.

35 2. The device of claim 1 wherein at least one removable sensor module is designed to attach to another removable sensor module in a stacked arrangement in a manner such that both removable modules connect to a sensor module interface unit.

3. The device of claim 1 wherein at least one sensor

-18-

module interface unit is connected to a communications IC.

4. The device of claim 1 wherein at least one sensor module interface unit is connected directly with said main CPU of said base unit.

5. The device of claim 1 wherein at least one sensor module interface unit is connected to said main CPU of said base unit through an analog interface.

6. The device of claim 2 wherein at least one sensor module interface unit is connected through a multiplexer to
10 a communications IC.

7. The device of claim 2 wherein at least one sensor module interface unit is connected directly with said main CPU of said base unit.

8. The device of claim 2 wherein at least one sensor module interface unit is connected to said main CPU of said base unit through an analog interface.

9. The device of claim 3 wherein said one or more removable sensor module includes a glucose meter.

10. The device of claim 2 wherein said one or more removable sensor module includes a glucose meter.

11. The device of claim 3 wherein said one or more removable sensor module includes a prothrombic time assay module for performing general coagulation measurements.

12. The device of claim 2 comprising a removable glucose meter mounted from a prothrombic time assay module.

13. The device of claim 1 wherein said one or more removable sensor module includes a glucose meter.

14. The device of claim 1 wherein said one or more removable sensor module includes a module for performing
30 general coagulation measurements.

15. The device of claim 3 including a plurality of sensor module interface units connected through a multiplexer to said communications IC.

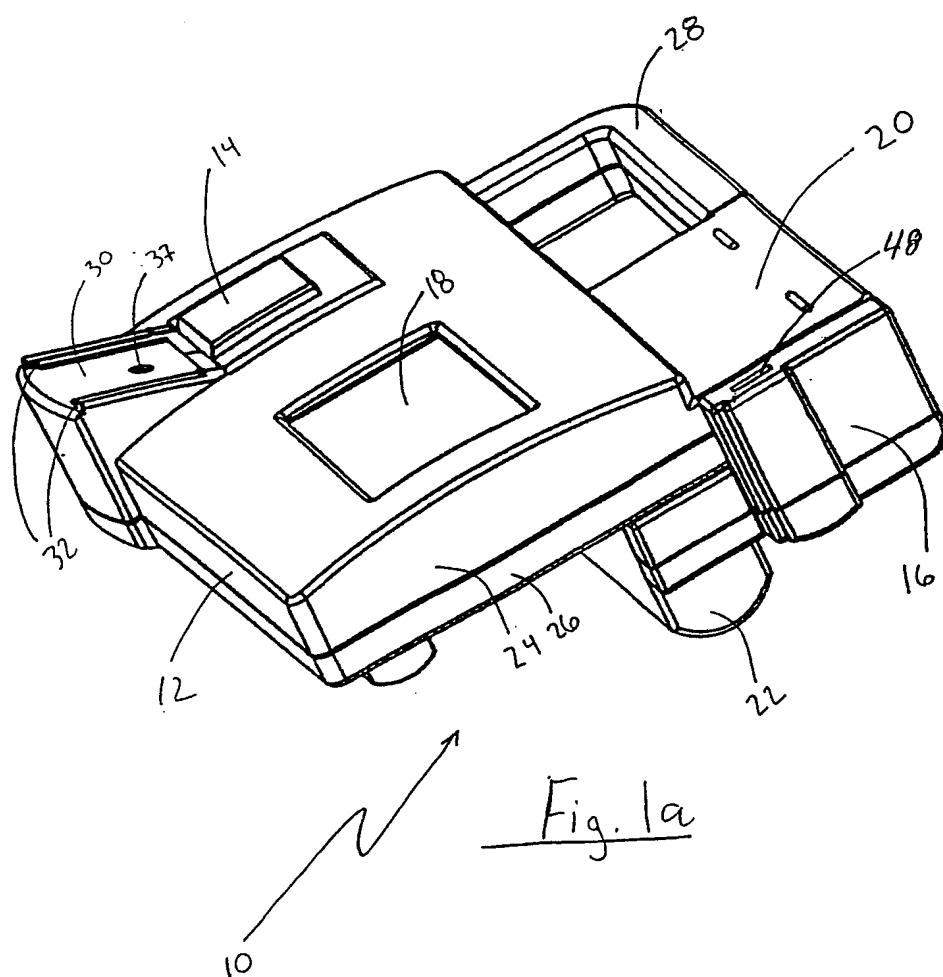
16. The device of claim 14 wherein said general coagulation measurements include prothrombin time (PT), activated partial thrombo-plastin time (PTT) and activated clotting time (ACT).

-19-

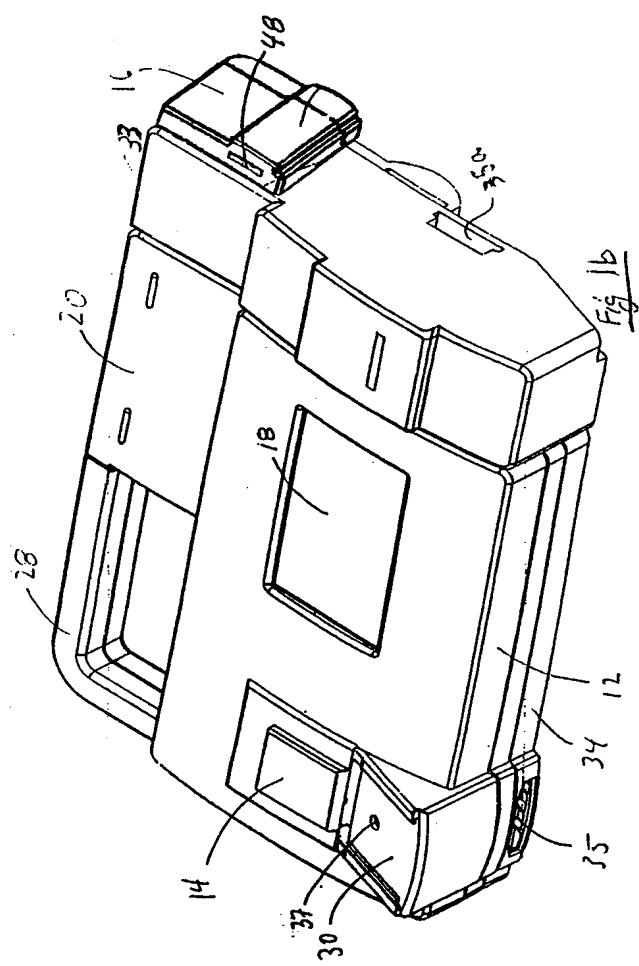
17. The device of claim 1 wherein said one or more dedicated removable sensor modules includes a visible light sensing device that makes co-oximetry measurements.

18. The device of claim 1 wherein said co-oximetry measurements include total hemoglobin concentrations (tHb), oxyhemoglobin (O₂Hb), carboxyhemoglobin (COHb) and methemoglobin (MetHb).

1/13



2/13



3/13

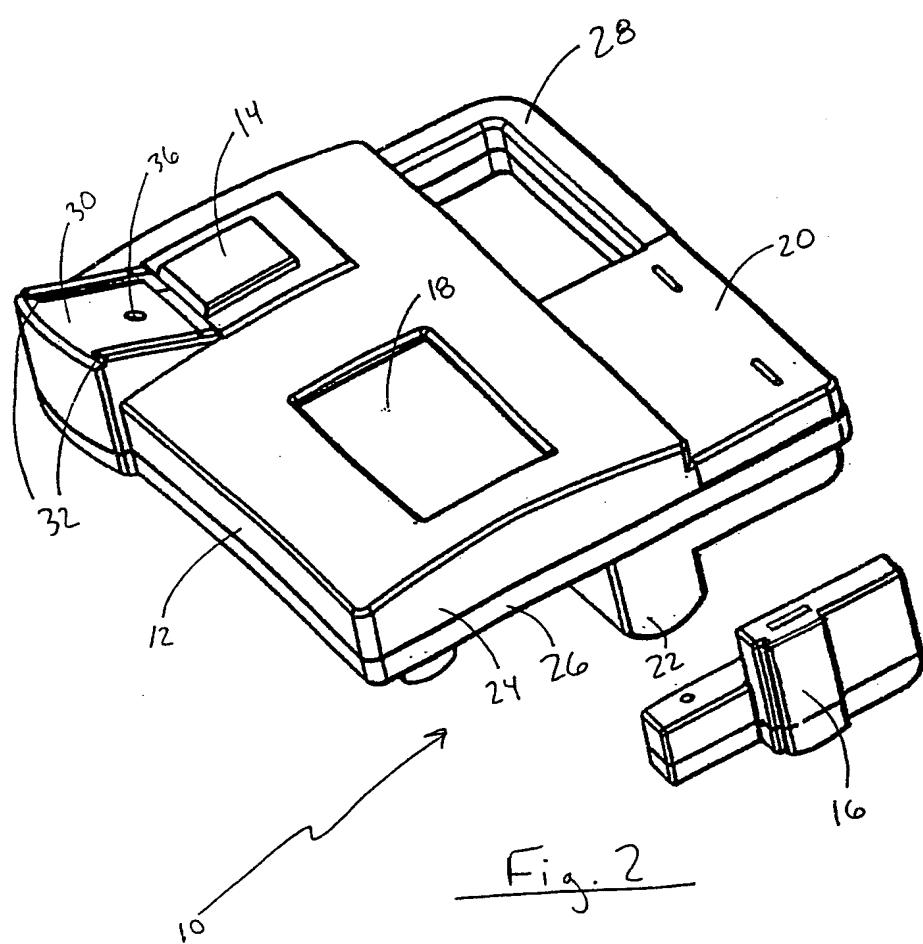


Fig. 2

4 / 13

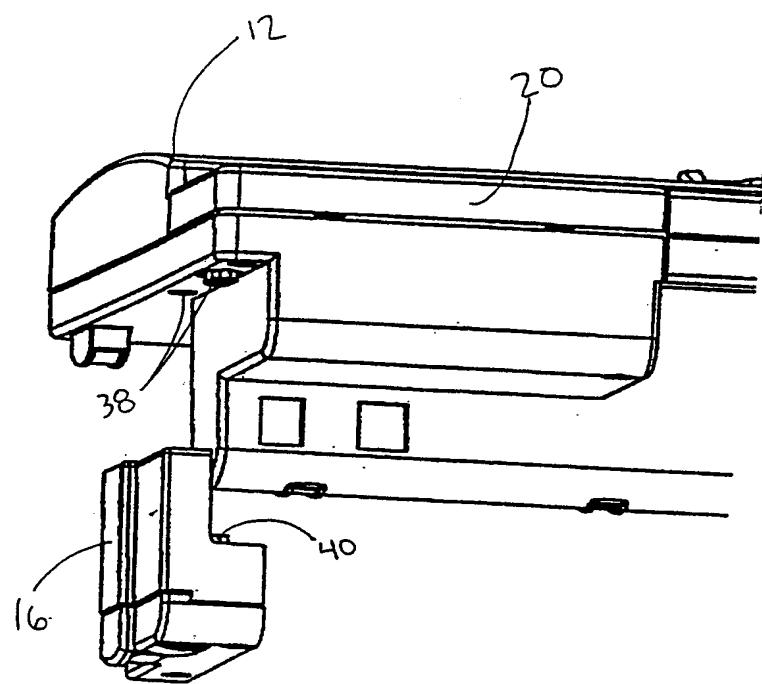
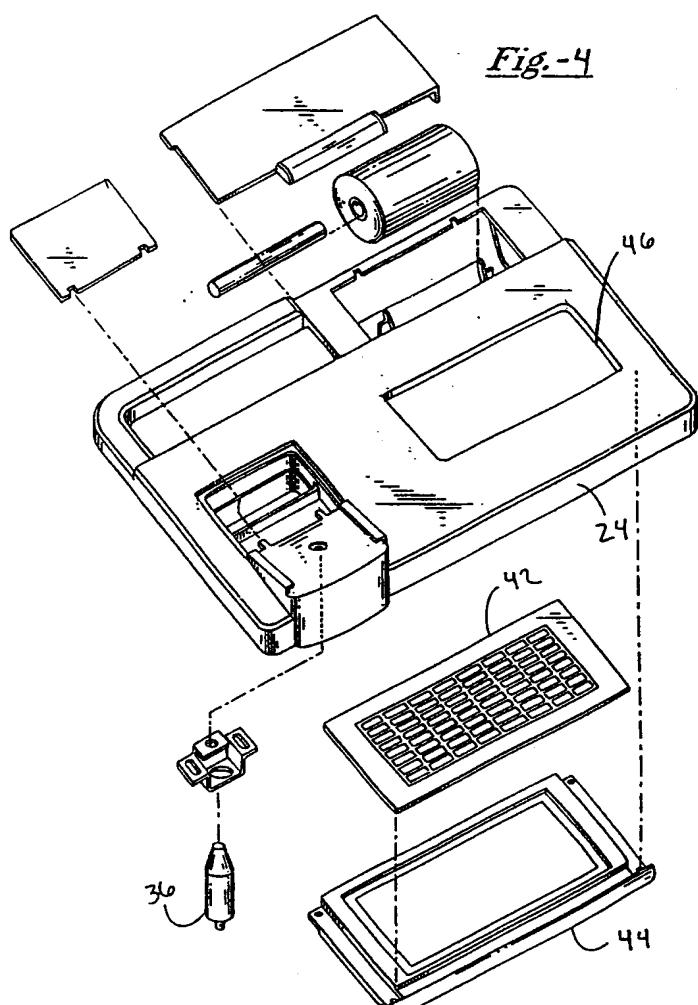
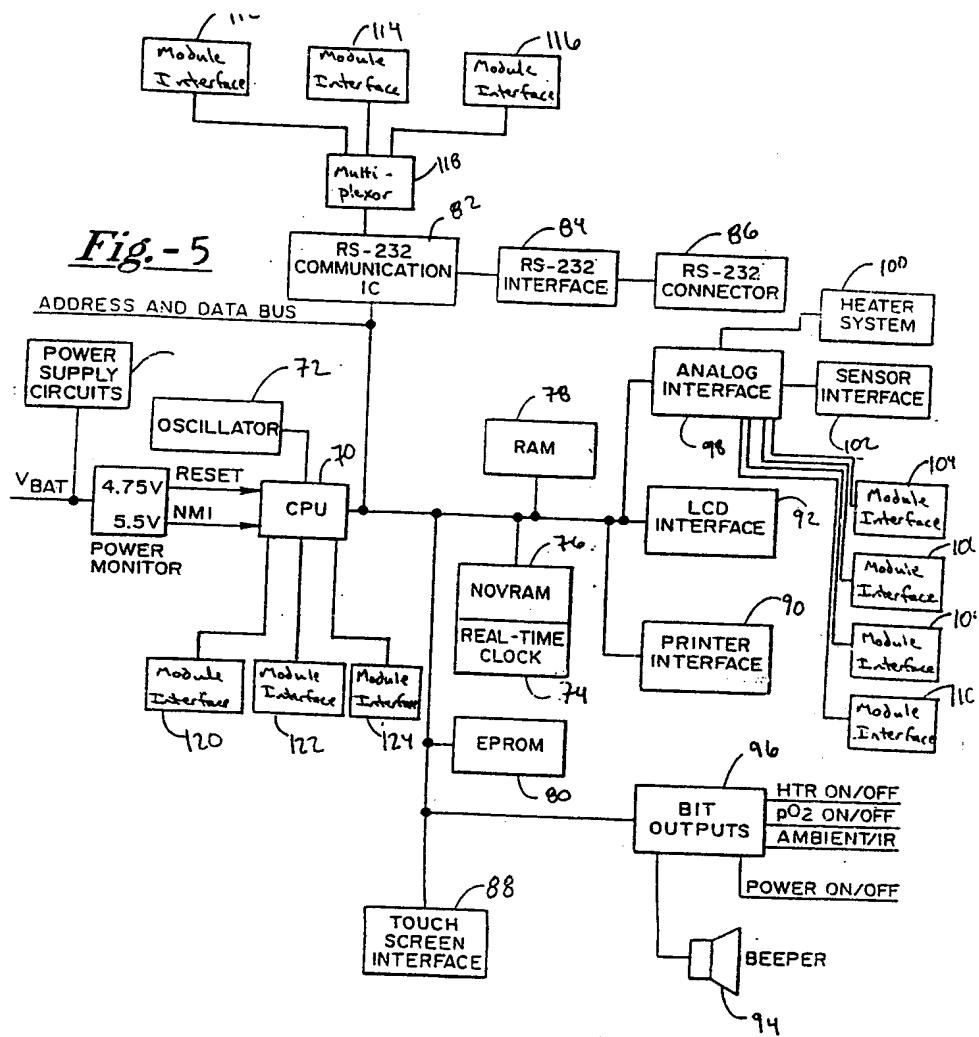


Fig. 3

5/13





7/13

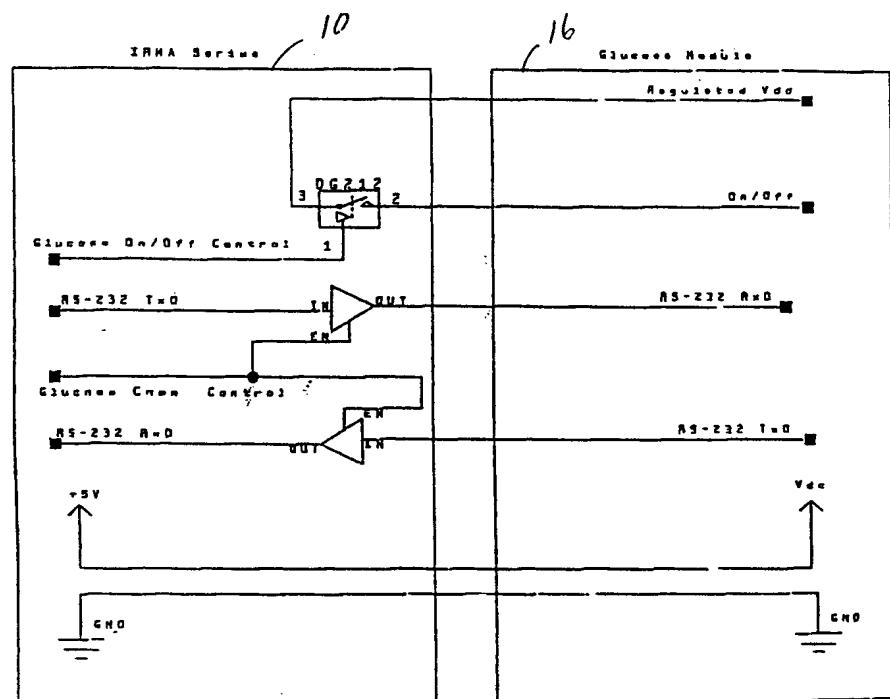
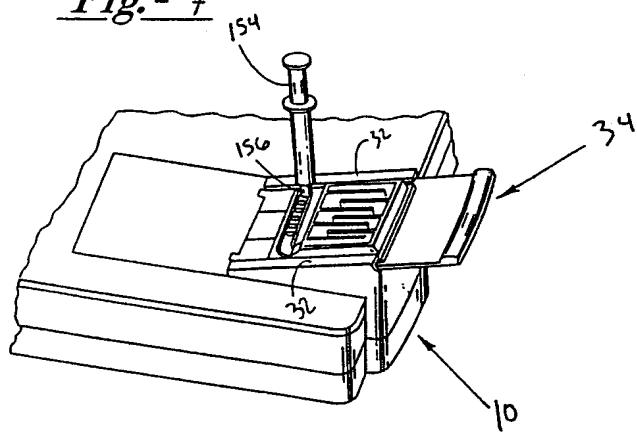
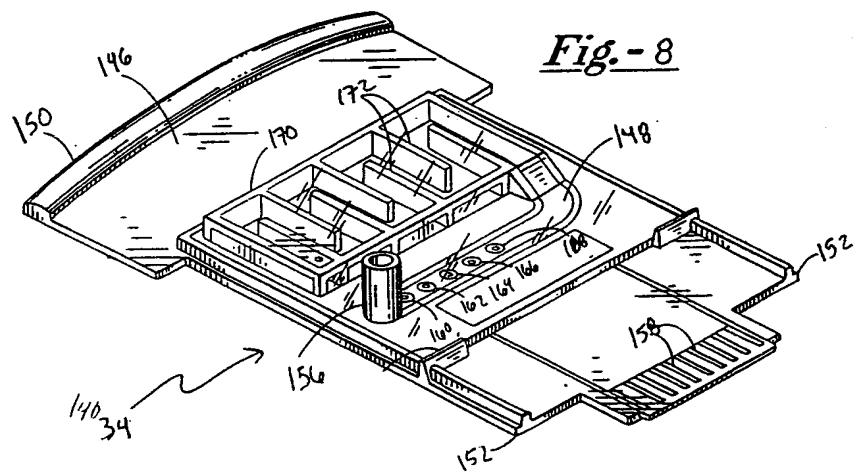
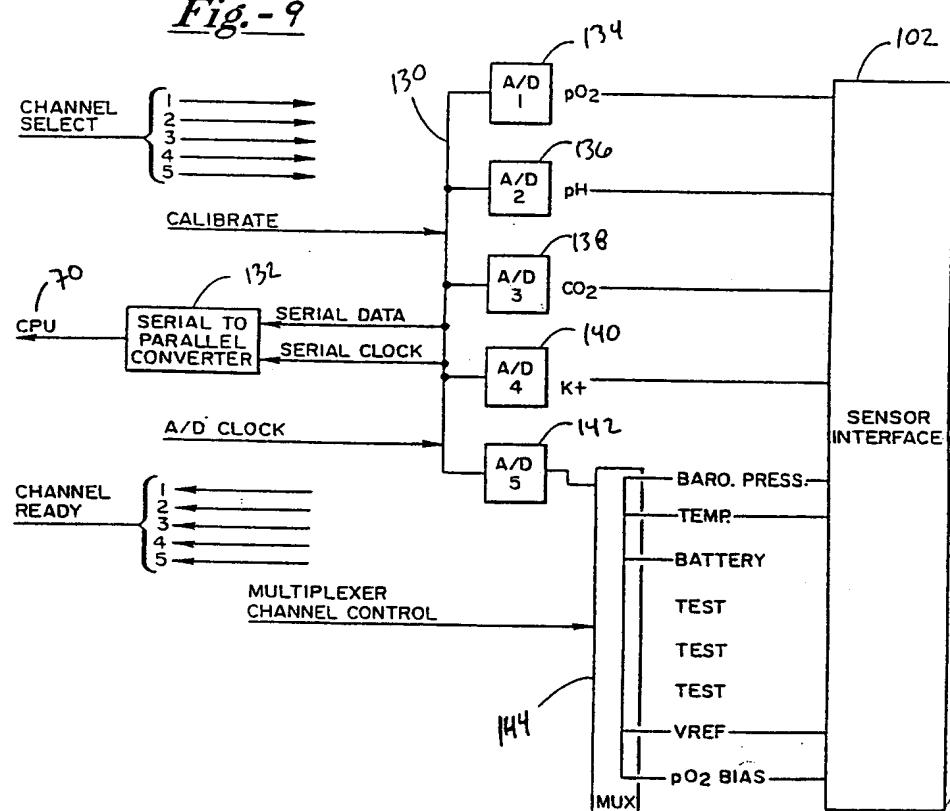


Fig. 6

8 / 13

Fig. - 7*Fig. - 8*

9/13

Fig. - 9

10/13

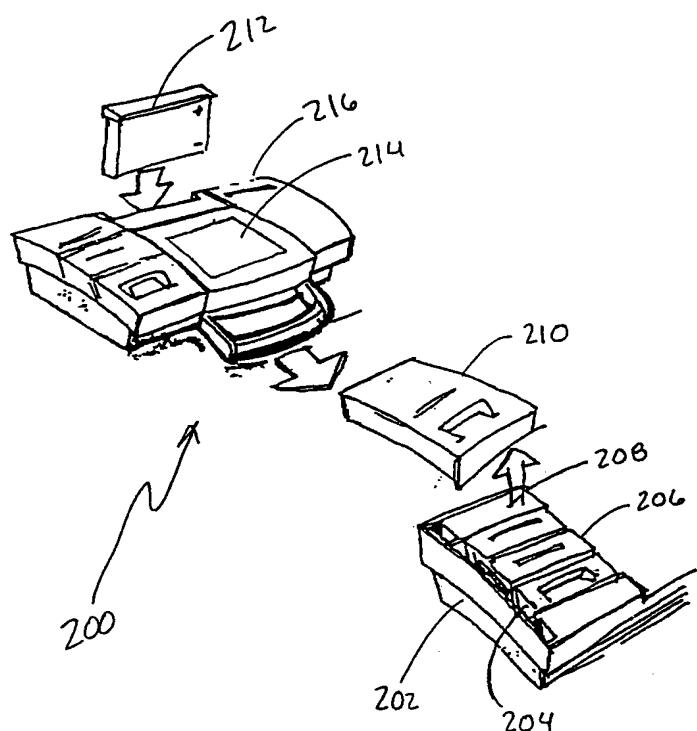


Fig. 10

11/13

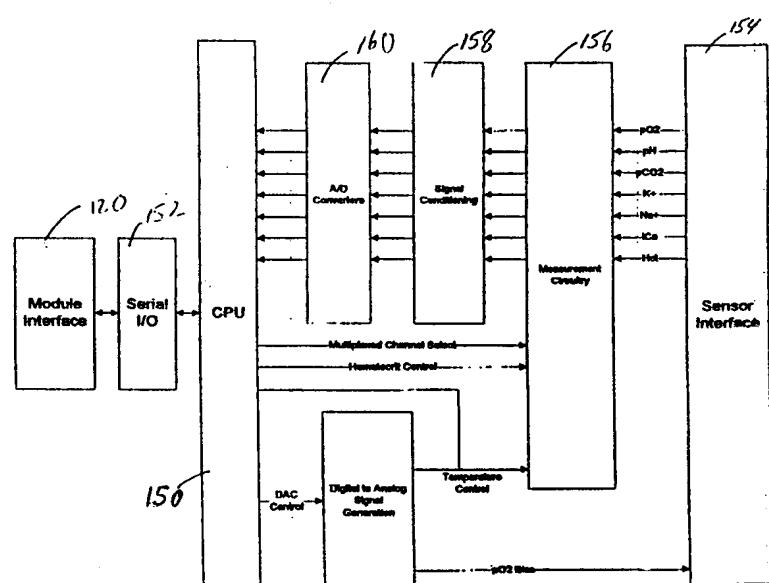


Fig 11

12/13

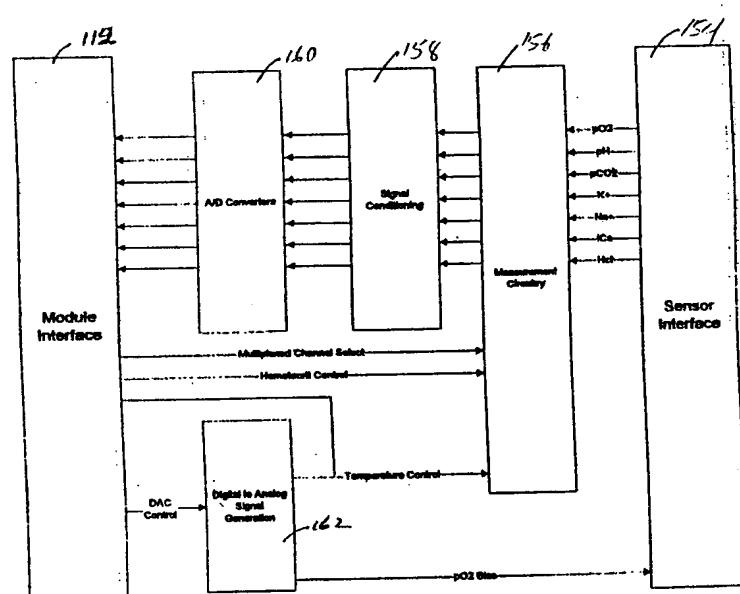


Fig 12

13/13

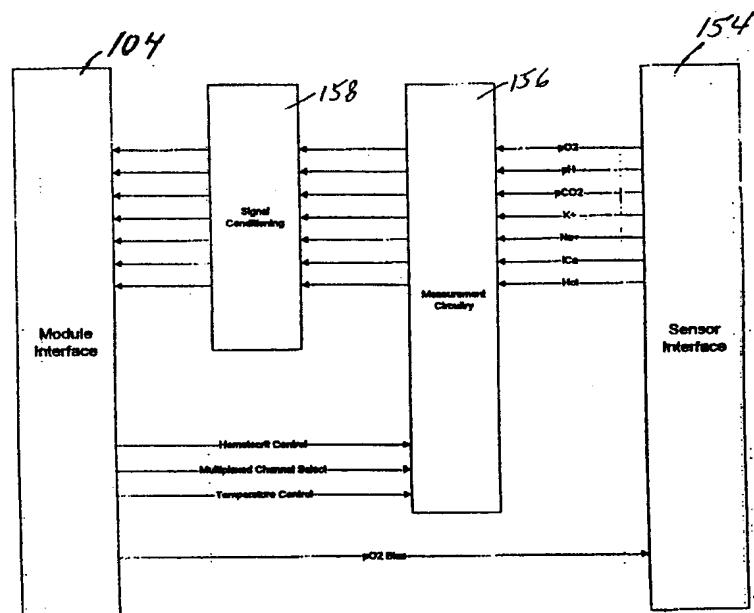


Fig 13

INTERNATIONAL SEARCH REPORT

International Application No

PL./US 99/14699

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N33/487

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 935 106 A (LISTON MAX D ET AL) 19 June 1990 (1990-06-19) column 6, line 32 -column 33, line 52; figures ---	1-18
A	US 4 849 340 A (OBERHARDT) 18 July 1989 (1989-07-18) the whole document ---	11-14, 16
A	WO 94 19684 A (DIAMETRICS MEDICAL INC) 1 September 1994 (1994-09-01) page 8, line 26 -page 17, line 18; figures ---	1-18
A	WO 94 19683 A (DIAMETRICS MEDICAL INC) 1 September 1994 (1994-09-01) page 9, line 4 -page 14, line 35; figures ---	1-18
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

12 November 1999

Date of mailing of the international search report

23/11/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Bosma, R

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 99/14699

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 017 339 A (MARSONER) 21 May 1991 (1991-05-21) column 4, line 24 -column 6, line 48; figures ---	1-18
A	US 5 563 042 A (PHILLIPS) 8 October 1996 (1996-10-08) the whole document ---	9, 10
A	WO 97 44672 A (SENDX MEDICAL, INC.) 27 November 1997 (1997-11-27) the whole document ---	1-18
A	US 5 781 024 A (BLOMBERG) 14 July 1998 (1998-07-14) the whole document -----	1-18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/14699

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 4935106	A 19-06-1990	DE 3635150	A	21-05-1987	
		ES 556607	A	01-04-1988	
		ES 557793	A	16-10-1988	
		FR 2591747	A	19-06-1987	
		GB 2183041	A	28-05-1987	
		IT 1196574	B	16-11-1988	
		JP 62119451	A	30-05-1987	
		US 4946651	A	07-08-1990	
US 4849340	A 18-07-1989	AT 120543	T	15-04-1995	
		AU 613623	B	08-08-1991	
		AU 1591888	A	02-11-1988	
		CA 1310566	A	24-11-1992	
		DE 3853457	D	04-05-1995	
		DE 3853457	T	26-10-1995	
		EP 0308494	A	29-03-1989	
		JP 1502797	T	28-09-1989	
		JP 2736091	B	02-04-1998	
		WO 8807666	A	06-10-1988	
		US 5110727	A	05-05-1992	
		US 5658723	A	19-08-1997	
WO 9419684	A 01-09-1994	AU 6245694	A	14-09-1994	
WO 9419683	A 01-09-1994	AU 6268994	A	14-09-1994	
US 5017339	A 21-05-1991	AT 391950	B	27-12-1990	
		AT 83088	A	15-06-1990	
		EP 0335859	A	04-10-1989	
		JP 1285861	A	16-11-1989	
US 5563042	A 08-10-1996	US 5426032	A	20-06-1995	
		US 5179005	A	12-01-1993	
		US 4935346	A	19-06-1990	
		US 5843692	A	01-12-1995	
		US 5304468	A	19-04-1994	
		AU 3375789	A	02-11-1989	
		CA 1337682	A	05-12-1995	
		DK 204289	A	29-10-1989	
		GR 89100286	A, B	31-01-1990	
		JP 1318963	A	25-12-1989	
		PT 90386	A, B	10-11-1989	
		AT 96179	T	15-11-1993	
		AT 174687	T	15-01-1999	
		AT 172538	T	15-11-1998	
		AT 172499	T	15-11-1998	
		AU 603821	B	29-11-1990	
		AU 7675887	A	18-02-1988	
		CA 1301604	A	26-05-1992	
		CN 1011919	B	06-03-1991	
		CN 1050930	A, B	24-04-1991	
		CN 1116307	A	07-02-1996	
		DE 3752229	D	26-11-1998	
		DE 3752229	T	02-06-1999	
		DE 3752230	D	26-11-1998	
		DE 3752230	T	06-05-1999	
		DE 3752241	D	28-01-1999	
		DE 3752241	T	17-06-1999	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/14699

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 5563042	A	DE	3787851	D	25-11-1993
		DE	3787851	T	21-04-1994
		DK	91594	A	05-08-1994
		DK	157092	A	29-12-1992
		DK	157192	A	29-12-1992
		DK	419187	A	14-02-1988
		EP	0256806	A	24-02-1988
		EP	0479394	A	08-04-1992
		EP	0473241	A	04-03-1992
		EP	0656423	A	07-06-1995
		EP	0816849	A	07-01-1998
		ES	2046985	T	16-02-1994
		ES	2126562	T	01-04-1999
		ES	2121766	T	16-12-1998
		ES	2124490	T	01-02-1999
		FI	873356	A, B,	14-02-1988
		FI	942818	A, B,	14-06-1994
		FI	951491	A	29-03-1995
		GR	3026514	T	31-07-1998
		GR	3029505	T	28-05-1999
		IE	64442	B	09-08-1995
		JP	2589053	B	12-03-1997
		JP	7067698	A	14-03-1995
-----	-----	-----	-----	-----	-----
WO 9744672	A	27-11-1997	AU	3076797	A
-----	-----	-----	-----	-----	09-12-1997
US 5781024	A	14-07-1998	WO	9900667	A
			AU	3396197	A
					07-01-1999
					19-01-1999
-----	-----	-----	-----	-----	-----